MANIPULATIVE THERAPY

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Table of Contents

<table>
<thead>
<tr>
<th>Benefit Considerations</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Coverage Rationale</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Description of Services</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Clinical Evidence</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>U.S. Food and Drug Administration</td>
<td>10</td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Centers for Medicare and Medicaid Services (CMS)</td>
<td>11</td>
</tr>
<tr>
<td>11</td>
<td></td>
</tr>
<tr>
<td>References</td>
<td>11</td>
</tr>
<tr>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Policy History/Revision Information</td>
<td>15</td>
</tr>
<tr>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

Related Policies:
- Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation
- Gait Analysis
- Home Traction Therapy
- Manipulation Under Anesthesia
- Motorized Spinal Traction
- Neuropsychological Testing Under the Medical Benefit
- Spinal Ultrasonography

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.
COVERAGE RATIONALE

Manipulative therapy is proven and medically necessary for treatment of musculoskeletal disorders, except as noted below.

Manipulative therapy is unproven and not medically necessary for treatment of:

- Non-musculoskeletal disorders (e.g., asthma, otitis media, infantile colic, etc)
- Prevention/maintenance/custodial care
- Internal organ disorders (e.g., gallbladder, spleen, intestinal, kidney, or lung disorders)
- Temporomandibular Joint (TMJ) Disorder
- Scoliosis correction
- Craniosacral therapy (cranial manipulation/Upledger technique)
- Manipulative services that utilize nonstandard techniques such as applied kinesiology technique, NUCCA, network and neural organizational technique

The role of manipulation for the above has not been established in scientific literature. A beneficial impact on health outcomes, e.g., improved physical function, durable pain relief, has not been established.

Manipulative therapy is unproven and not medically necessary when ANY of the following apply:

1. The patient’s condition has returned to the pre-symptom state.
2. Little or no improvement is demonstrated within 30 days of the initial visit despite modification of the treatment plan.
3. Concurrent manipulative therapy, for the same or similar condition, provided by another health professional whether or not the healthcare professional is in the same professional discipline.

This policy does not address manipulation under anesthesia; refer to the Medical Policy titled Manipulation Under Anesthesia.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

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<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
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<td>98925</td>
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<tr>
<td>98926</td>
<td>Osteopathic manipulative treatment (OMT); three to four body regions involved</td>
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<td>98927</td>
<td>Osteopathic manipulative treatment (OMT); five to six body regions involved</td>
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<td>98928</td>
<td>Osteopathic manipulative treatment (OMT); seven to eight body regions involved</td>
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<td>98929</td>
<td>Osteopathic manipulative treatment (OMT); nine to ten body regions involved</td>
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<tr>
<td>98940</td>
<td>Chiropractic manipulative treatment (CMT); spinal, one to two regions</td>
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MANIPULATIVE THERAPY: MEDICAL POLICY (EFFECTIVE 06/01/2014)

DESCRIPTION OF SERVICES

Manipulative treatment, also known as mobilization therapy or “adjustment,” refers to manual therapy employed to soft or osseous tissues for therapeutic purposes. This term encompasses a wide variety of physical manipulations, including rhythmic stretching, deep pressure and traction, and spinal adjustments. Spinal manipulation involves manual and mechanical interventions that may be high or low velocity; short or long lever; high or low amplitude; with or without recoil. Most often, manipulation is performed by applying a controlled force into a joint or joints of the spinal column to reduce or correct a specific derangement. Depending on the provider specialty, a joint derangement may be listed as a subluxation, vertebral subluxation complex, osteopathic lesion, somatic dysfunction or a mechanical dysfunction.

Craniosacral therapy is a noninvasive osteopathic technique that involves the therapist touching the patient to detect pulsations and rhythms of flow of cerebrospinal fluid (CSF). The therapist then gently works with the skull and spine, with the goal to effect release of potential restrictions to the flow of CSF, without the use of forceful physical manipulation. (Hayes, 2009)

Manipulative treatment has been proposed as either a singular intervention or a part of combined approach in the prevention of health-related disorders. (Axen 2009) Individuals may elect to receive care that may mitigate the development of a disorder i.e., primary prevention. Clinicians may provide manipulative therapy in an attempt to prevent new events (secondary prevention) or maintain patients at their best possible level once improvement has been achieved (tertiary prevention). This type of care is typically termed maintenance or custodial care. Other analogous terms include wellness, elective, preventive, and palliative care.

CLINICAL EVIDENCE

Manipulative therapy is most often performed on the spine and pelvis for musculoskeletal disorders. Its use has been investigated for a range of disorders.

Musculoskeletal Disorders

A 2013 cohort study by Leeman et al. evaluated 148 patents between the ages of 18 and 65 with low back and leg pain due to MRI confirmed herniated disc, who were being treated with high velocity and low amplitude spinal manipulation in terms of their short-, medium-, and long-term outcomes of self-reported global impression of change and pain levels at various time points up to 1 year and to determine if outcomes differ between acute and chronic patients using a prospective, cohort design. The type of manipulation was dependent upon whether the disc herniation was intraforaminal or paramedian as seen on the magnetic resonance images and was performed by a doctor of chiropractic. Outcomes included the patient's global impression of change scale for overall improvement, the NRS for LBP, leg pain, and the Oswestry questionnaire at 2 weeks, 1, 3, and 6 months, and 1 year after the first treatment. The proportion of patients reporting "improvement" on the patient's global impression of change scale was calculated for all patients and acute vs. chronic patients. At the conclusion of the study a large
percentage of acute and importantly chronic lumbar disc herniation patients treated with chiropractic spinal manipulation reported clinically relevant improvement.

A 2011 Cochrane review by Rubinstein et al. (2011) evaluated 26 randomized controlled trials that assessed the effects of spinal manipulative therapy (SMT) in 6070 patients with chronic low-back pain. They concluded that SMT appears to be as effective as other common therapies prescribed for chronic low-back pain, such as, exercise therapy, standard medical care or physiotherapy. However, it is less clear how it compares to no treatment or sham (placebo) treatment.

In a 2010 Cochrane review by Walker et al., 12 studies involving 2887 participants were evaluated to assess the various combinations of chiropractic care for low-back pain. The review showed that while combined chiropractic interventions slightly improved pain and disability in the short term and pain in the medium term for acute and subacute low-back pain, there is currently no evidence to support or refute that combined chiropractic interventions provide a clinically meaningful advantage over other treatments for pain or disability in people with low-back pain.

A 2010 Cochrane review of manipulation or mobilization for neck pain included 27 trials involving 1522 participants. The authors concluded cervical manipulation and mobilization may provide immediate- or short-term change; however, no long-term data are available. Thoracic manipulation may improve pain and function. Optimal techniques and dose are unresolved. (Gross, 2010) Further research is needed to establish whether cervical manipulation provides long-term relief.

A meta-analysis by Chou et al. (2007) evaluated non-pharmacologic therapies for acute and chronic low back pain and found that there is good evidence spinal manipulation is moderately effective for subacute and chronic low back pain; and fair evidence for small to moderate benefits for acute low back pain.

Dagenais et al. (2010) conducted a systematic review to evaluate spinal manipulation therapy for low back pain. Of 699 studies, 14 (n = 2,027 patients) were included for review. Spinal manipulation therapy was most commonly compared to physical modalities, education, medication, exercise, mobilization, or sham therapy. The authors found that the results from most studies suggest that 5 to 10 sessions of spinal manipulation therapy administered over 2 to 4 weeks achieve equivalent or superior improvement in pain and function when compared with other commonly used interventions for short, intermediate, and long-term follow-up.

A systematic review by Licciardone et al. (2005) of 6 osteopathic manipulative treatment (OMT) clinical trials were evaluated to assess the efficacy of OMT as a complementary treatment for low back pain. A total of 525 subjects with low back pain were randomized in the eligible trials. Overall, OMT significantly reduced low back pain (effect size, -0.30; 95% confidence interval, -0.47 - -0.13; P = .001). Stratified analyses demonstrated significant pain reductions in trials of OMT vs. active treatment or placebo control and OMT vs. no treatment control. The authors concluded that OMT significantly reduces low back pain and the level of pain reduction was greater than expected from placebo effects alone. This review was limited by the various study designs such as the methodology, trial setting, subject characteristics, OMT and control treatment interventions, and pain measures.

Bronfort et al. (2010) conducted a comprehensive review of the effectiveness of manual therapies including manipulation and found spinal manipulation effective for the treatment of acute low back pain, acute/subacute neck pain, and chronic neck pain (when combined with exercise). However, the evidence for cervical manipulation/mobilization for tension type headaches as well as manipulation alone for coccydynia, sciatica and fibromyalgia was inconclusive. There is a paucity of evidence of the effectiveness of spinal manipulation for treatment of headaches.
Vernon et al (2009) report that only 2 clinical trials of spinal manipulation for adult tension type headache have been reported, neither of which was fully controlled.

Leaver et al. (2010) conducted a randomized controlled trial comparing manipulation with mobilization for recent onset of neck pain in 182 patients. Patients were randomly assigned to receive 4 treatments of either neck manipulation (n=91) or mobilization (n=91) over 2 weeks. Outcomes were measured by the number of days taken to recover from the episode of neck pain. Median days to recovery were 47 for the manipulation group and 43 days for the mobilization group. The authors concluded that manipulation was no more effective than mobilization in treating recent onset of neck pain.

A prospective, multicenter study by Rubinstein et al. (2007), evaluated 529 patients with neck pain to assess clinical outcomes and adverse events. Follow-up occurred at 3 and 12 months using questionnaires. Fifty-six percent of patients reported worsening of symptoms or onset of a new symptom during any one of the first 3 treatments. Only 5 patients (1%) reported to be much worse at 12 months. No serious adverse events were recorded during the study period. The authors concluded that while adverse events may be common, they are rarely severe in intensity. Most patients report recovery, particularly in the long term. Therefore, the benefits of chiropractic manipulative therapy for neck pain seem to outweigh the potential risks.

Non-musculoskeletal Disorders (e.g., asthma, otitis media, infantile colic, etc)
Ferrance and Miller (2010), conducted a recent systematic review found that chiropractors treat a wide variety of pediatric health conditions, but that those interventions are supported by only low levels of scientific evidence, most of which is clinical experience, descriptive case studies and very few observational and experimental studies. The more scientifically rigorous studies show conflicting results for colic and the crying infant, and there is little data to suggest improvement of otitis media, asthma, nocturnal enuresis or attention deficit hyperactivity disorder.

Bronfort et al. (2010) conducted a comprehensive review on the effectiveness of manual therapies including manipulation for various non-musculoskeletal disorders. While not all studies compare manipulation to sham manipulative treatment, the evidence for spinal manipulation did not support its effectiveness for asthma, dysmenorrhea, stage 1 hypertension, premenstrual syndrome, pneumonia, otitis media, enuresis, and infantile colic. Other systematic reviews have arrived at similar conclusions. (Ernst, 2001; Hondras, 2001; Hughes and Bolton, 2002; Mills et al., 2003; Hawk et al., 2007; Pohlman et al., 2012)

Prevention (primary, secondary, tertiary) for Maintenance Care
Once maximum therapeutic benefit from chiropractic care has been obtained, additional chiropractic care may be considered as elective preventive/maintenance care or supportive care.

Prevention for maintenance/custodial are is defined as elective healthcare that is typically long-term, not therapeutically necessary, but provided at intervals to prevent disease, prolong life, promote health and enhance quality of life. Evidence in the published, peer-reviewed, scientific literature has not shown that preventive chiropractic services are effective and improve long-term clinical outcomes.

Martel et al. (2011) conducted a randomized controlled trial to compare the efficacy of preventive spinal manipulative therapy (SMT) to no treatment in 108 patients with non-specific chronic neck pain. The trial was divided into 2 phases. The first was the non-randomized, symptomatic phase during which all eligible participants received a short course of SMT. Ten patients dropped out of the study following the symptomatic phase. After completing the symptomatic phase, the remaining 98 participants were randomly assigned to 1 of 3 parallel groups (no treatment (n = 29), a SMT group (n = 36) or a SMT plus exercise group (n = 33)). The second preventive phase lasted 10 months. Outcomes were measured using visual analog scale (VAS), active cervical
ranges of motion (cROM), the neck disability index (NDI) and the Bournemouth questionnaire (BQ). Patients were also asked to keep an exercise diary. Mean adherence to the home exercise program was 48.8%. In the preventive phase, all 3 groups showed outcomes scores similar to those obtain following the non-randomized, symptomatic phase. Overall spinal manipulation or spinal manipulation combined with exercises did not have any significant advantages when compared to the no treatment strategy. The authors found that preventive therapy was no more effective than no treatment at all for patients with non-specific chronic neck pain.

A randomized controlled trial by Senna and Machaly (2011) investigated the effects of maintenance spinal manipulation therapy for chronic non-specific low back pain. Subjects were randomized into 3 groups and followed for 10 months. Group 1 (n=40) received sham manipulation during the first month and no treatment over the subsequent 9 months. Group 2 (n=27) received manipulation during the first month but no treatment during the following 9 months. Group 3 (n=26) received manipulation during the first month and ‘maintenance’ manipulation every 2 weeks for an additional 9 months. At the end of 10 months, 33 subjects declined follow-up. Five withdrew in the first phrase before treatment began. Of the remaining 88 subjects, 80 were evaluated at 4 months, 71 at 7 months and 60 at 10 months. Subjects in groups 2 and 3 experienced significantly lower pain and disability scores compared to the control group after the initial 1-month treatment period. At the end of 10 months, group 3 reported significantly lower pain and disability scores compared to Group 2. The authors concluded that spinal manipulation is an effective treatment for chronic non-specific low back pain. While Group 3 reported better outcomes, the basis of this improvement could not be determined as to whether it was the manipulation or the placebo effect of continued visits. The study is further limited by serious methodological flaws e.g., 35% drop-out rate; incomplete outcome data; lack of blinding; and uncertainty about allocation concealment, use of co-interventions, and compliance across groups.

In a review, Aker and Martel (1996) concluded, “There is no scientifically valid research to support the assumption that spinal manipulation alone is a viable health promotion strategy.” A more recent review has been published. (Leboeuf-Yde and Hestbaek, 2008) The authors reached several conclusions. “There is no evidence-based definition of maintenance care and the indications for and nature of its use remains to be clearly stated. It is likely that many chiropractors believe in the usefulness of maintenance care but it seems to be less well accepted by their patients. The prevalence with which maintenance care is used has not been established. Efficacy and cost-effectiveness of maintenance care for various types of conditions are unknown.”

Axen at al. (2009) conducted a survey of 167 chiropractors to explore what factors chiropractors consider before recommending maintenance care to patients with low back pain (LBP). Based on the survey the authors concluded chiropractic treatment can prevent relapses of back pain; however, this is based on professional opinion and not patient outcomes.

Beyond a broad conceptual approach, there does not appear to be a consensus on the clinical application of maintenance/custodial care. “The indications for maintenance care and clear descriptions of preventive treatment for specific types of conditions are not found in the literature.” (Axen 2008) With the exception of a pilot study, the general concepts of how to proceed over time with this type of patient are lacking.

Internal Organ Disorders
A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated manipulative therapy of internal organs such as the gallbladder, spleen, intestines, kidneys or lungs.
Temporomandibular Joint (TMJ) Disorders
The available published studies are primarily case reviews, uncontrolled or general review articles.

Three small randomized controlled trials evaluating temporomandibular joint disorders were identified. Monaco (2008) evaluated 28 subjects where kinesiographic tracings were used to assess the effects of osteopathic manipulative treatment (OMT) on the parameters of maximal mouth opening and movement velocities. Patient-centered outcomes of pain and function were not assessed. Clinical trials by Taylor et al. (1994) and Carmeli et al. (2001) were included in three systematic reviews.

A comprehensive review by Bronfort et al. (2010) found that the evidence for treating TMJ disorders with manipulation is inconclusive.

Two reviews by McNeely et al. (2006) and Medlicott and Harris (2006) concluded there is limited evidence for the use of manual therapy in the treatment of temporomandibular joint dysfunction.

There is insufficient evidence that manipulation of the TMJ will result in fewer symptoms or improve functionality.

Scoliosis
Manipulative care has been utilized for the treatment of idiopathic scoliosis however evidence is lacking; the efficacy of manual therapy for correcting the scoliotic curve or progression of the curve has not been established in the peer-reviewed published scientific literature.

In a systematic literature review of non-surgical treatment in adult scoliosis, Everett and Patel (2007) stated that there is only very weak evidence for the use of manipulation in adult deformity.

A systematic review by Romano and Negrini (2008) reviewed 73 papers, mainly case series, regarding manual therapy for idiopathic adolescent scoliosis. Only 3 papers were relevant to their study however none of the 3 satisfied all the required inclusion criteria because they were characterized by a combination of manual techniques and other therapeutic approaches. The authors found insufficient data to develop any conclusions on the efficacy of manual therapy for the treatment of adolescent idiopathic scoliosis.

Hasler et al. (2010) conducted a small (n=20) prospective controlled trial that investigated the effectiveness of osteopathic manual interventions (visceral and cranial manipulation) on trunk morphology in adolescent idiopathic scoliosis (AIS). The results showed no therapeutic effect on rib hump, lumbar prominence, plumb line, sagittal profile and global spinal flexibility. The authors concluded they found no evidence to support osteopathic manual therapy for the treatment of mild AIS.

A prospective study by Glassman et al. (2010) evaluated the value of non-operative treatment, including manipulation, commonly used for adult scoliosis patients. There was no improvement in quality of life and disability measures observed over a minimum of 2-year follow-up within the subgroup of patients who elected to receive manipulative treatment. Similarly, there were no differences between groups including those who did not receive any treatment.

Extremity Disorders
A comprehensive review by Bronfort et al. (2010) evaluated the effectiveness of manual therapies including manipulation for a broad range of extremity disorders. The following had positive results: shoulder girdle pain and dysfunction, adhesive capsulitis, hip osteoarthritis, knee osteoarthritis, patello-femoral syndrome, and plantar fasciitis (when combined with exercise).
Shoulder
Ho et al. (2009) conducted a systematic review of 14 randomized controlled trials to evaluate the effectiveness of manual therapy (MT) techniques (including massage, joint mobilization and manipulation) for shoulder disorders. Results were analyzed within diagnostic subgroups (adhesive capsulitis (AC), shoulder impingement syndrome [SIS], non-specific shoulder pain/dysfunction) and a qualitative analysis using levels of evidence to define treatment effectiveness was applied. The authors concluded there was no clear evidence to suggest additional benefits of manual therapy to other interventions for shoulder impingement syndrome. The findings of the higher quality studies, however, favored manual therapy for pain reduction over exercise-alone and conventional physiotherapy-alone. Ranges of motion (ROM) outcomes were equivalent between groups receiving manual therapy and conventional physiotherapy. Studies that measured shoulder function favored the addition of manual therapy to exercises and were more effective than other physiotherapy procedures employed. In contrast, manual therapy was no more effective than other interventions in improving pain, range of motion, and function for the treatment of adhesive capsulitis. For non-specific shoulder pain/dysfunction, manual therapy was effective in reducing pain and short-term active range of motion, when compared to control groups and sham treatment. Perceived recovery favored manual therapy at both short-term and long-term follow-up.

Green et al. (2003) conducted a Cochrane review of 26 trials evaluating physiotherapy interventions for shoulder pain. Of the 26 trials included in the review, only 3 studies evaluated manual therapy and mobilization with and without exercise. The authors noted that combining mobilization with exercise resulted in additional benefit when compared to exercise alone for rotator cuff disease; however the same is not true for adhesive capsulitis.

Bergman et al. (2004) conducted a randomized, controlled trial of 150 patients with shoulder symptoms and dysfunction of the shoulder girdle. Patients were evenly allocated to receive manipulative therapy plus usual medical care (n=79) or usual medical care alone (n=71). Patients were prescribed oral analgesics or nonsteroidal anti-inflammatory drugs if necessary and if this was not effective, patients could receive up to 3 corticosteroid injections. Patients were followed for 52 weeks. Outcomes were measured by patient-perceived recovery, severity of the main complaint, shoulder pain, shoulder disability, and general health. During treatment (6 weeks), no significant differences were found between study groups. After completion of treatment (12 weeks), 43% of the intervention group and 21% of the control group reported full recovery. After 52 weeks, approximately the same difference in recovery rate (17 percentage points) was seen between groups. The authors concluded that manipulative therapy for the shoulder girdle in addition to usual medical care accelerates recovery of shoulder symptoms.

A prospective study by Mintken et al. (2010) utilized 5 prognostic factors associated with shoulder pain in 80 individuals to determine if cervical and thoracic spine manipulation would improve pain and disability. Participants underwent a standardized examination and then a series of thrust and non-thrust manipulations directed toward the cervicothoracic spine. Outcomes were measured using a 15-point Global Rating of Change (GROC) scale as well as outcomes from the prognostic variables. The GROC scale ranges from -7 (“a very great deal worse”) to 0 (“about the same”) to +7 (“a very great deal better”). Patients who rated their score as +4 or better were categorized as having a successful outcome. A total of 49 patients (61%) experienced a successful outcome. Mean Shoulder Pain and Disability Index (SPADI) scores decreased by more than 50% (from 38.1 to 18.4) in the successful group compared to 18% (from 37.9 to 30.4) in the non-successful group. Numeric pain rating scale (NPRS) scores also showed greater improvements in the successful group compared to the non-successful group. The participants’ ability to flex the shoulder without pain improved significantly in both groups. The authors found that if 3 of the 5 variables were present, the chance of achieving a successful outcome improved from 61% to
The study is limited by small sample size, lack of a control group and no long term follow-up.

**Elbow, Wrist or Hand**

Two systematic reviews encompassing a range of physiotherapies for lateral epicondylitis concluded the evidence is insufficient for most physiotherapy interventions including manipulation or mobilization. (Bisset et al., 2005; Smidt et al., 2003)

Two systematic reviews that included an assessment of extraspinal manipulation or mobilization for carpal tunnel syndrome reached disparate conclusions. A Cochrane review by O'Connor et al. (2003) of non-surgical treatment (other than steroid injection) for carpal tunnel syndrome concluded, "Current evidence shows significant short-term benefit from oral steroids, splinting, ultrasound, yoga and carpal bone mobilization... More trials are needed to compare treatments and ascertain the duration of benefit." Goodyear-Smith (2004) also authored a systematic review of nonsurgical treatment options for carpal tunnel syndrome. This review found, "The evidence does not support the use of nonsteroidal anti-inflammatory drugs, diuretics, pyridoxine (vitamin B₆), chiropractic [manipulative] treatment, or magnet treatment."

In a comparative study by Struijs et al. (2003), 31 patients with lateral epicondylitis were randomly assigned to receive either manipulation of the wrist (n=15) or ultrasound, friction massage, and muscle stretching and strengthening exercises (n=16). Follow-up was at 3 and 6 weeks with 3 patients electing to drop out of the study. After 3 and 6 weeks of intervention, no differences in mean improvement in range of motion was found within or between the groups. The authors were unable to definitively conclude the effectiveness of manipulation and recommend further research with randomization, and longer-term follow-up to further evaluate the use of manipulation for lateral epicondylitis.

**Hip Osteoarthritis**

A randomized clinical trial by Hoeksma et al. (2004) evaluated 109 patients with osteoarthritis of the hip to compare the effectiveness of a manual therapy (n=56) with exercise therapy (n=53) with a mean age of 72 years. The manual therapy group received therapy including manipulations and vigorous stretching while the control group received standard exercise therapy, which may have included stretching but did not include manipulation. The treatment period was 5 weeks (9 sessions). Outcomes were measured by general perceived improvement after treatment, level of pain, hip function, walking speed, range of motion, and quality of life. No major differences were found on baseline characteristics between groups. Success rates (primary outcome) after 5 weeks were 81% in the manual therapy group and 50% in the exercise group. Furthermore, patients in the manual therapy group had significantly better outcomes on pain, stiffness, hip function, and range of motion with results maintained after 29 weeks. The authors concluded that manual therapy is superior to exercise therapy for patients with OA of the hip.

**Knee Osteoarthritis**

Licciardone et al. (2004) conducted a randomized controlled trial of 30 patients who recently underwent surgery for knee osteoarthritis to evaluate the efficacy of osteopathic manipulative treatment (OMT) in the hospital setting. Patients were randomly assigned to receive either OMT or sham treatment. Patients receiving OMT for knee osteoarthritis had longer length of stays, decrease efficiency in rehabilitation and vitality. The authors concluded that osteopathic manipulative treatment does not appear to be efficacious in this hospital rehabilitation population.

**Ankle and Foot**

Cleland et al. (2009) conducted a multicenter randomized clinical trial of 60 patients with plantar heel pain to compare the effectiveness of electrophysical agents and exercise (EPAX) which included iontophoresis with dexamethasone and stretching of the gastrocnemius muscle and/or plantar fascia or a manual physical therapy and exercise (MTEX) which included aggressive soft tissue mobilization directed at the triceps surae and the insertion of the plantar fascia at the
medial calcaneal tubercle. Patients were equally split between the control and treatment groups and followed for 6 months. Outcomes were measured utilizing a number of patient self-report questionnaires, including the Lower Extremity Functional Scale (LEFS), the Foot and Ankle Ability Measure (FAAM), and the Numeric Pain Rating Scale (NPRS). The primary aim (effects of treatment on pain and disability) was examined with a mixed-model analysis of variance (ANOVA). Both groups demonstrated a significant improvement over time; however, the patients receiving in the MTEX group experienced greater clinical benefits in terms of function and pain than the patients in the EPAX group.

Three randomized controlled trials (Eisenhart et al., 2003; Green et al., 2001; Lopez-Rodriquez et al., 2007) evaluated the effects of manipulation on acute ankle sprain primarily in athletes. Two studies (Eisenhart et al., 2003; Lopez-Rodriquez et al., 2007), limited treatment to a single session while one study (Green et al., 2001) evaluated adjustments over 14 days (6 sessions).

A randomized trial by du Plessis et al. (2011) compared manual and manipulative therapy (MMT) with standard care of a night splint(s) for symptomatic mild to moderate hallux abducto valgus (HAV). Thirty patients were equally assigned to each group. The control group used a night splint(s) while the experimental group (MMT) received 4 MMT 4 treatments over a 2-week period. Outcomes were measured with visual analogue scale, foot function index and hallux dorsiflexion. Outcome measure scores in the control group (night splint) regressed between the 1-week follow-up and 1-month follow-up when patients did not use the night splint, while the scores in the experimental group (MMT) were sustained up to the 1-month follow-up. The authors concluded that a structured protocol of manual and manipulative therapy is equivalent to standard care of a night splint(s) for symptomatic mild to moderate HAV in the short term.

A pilot study by Pellow and Brantingham (2001) evaluated the use of manipulation in 30 patients with ankle sprain. Patients were equally divided to receive either an adjustment or ultrasound treatment over 4 weeks. While both groups showed improvement, the authors found that the adjustment group had greater reduction in pain, increased ankle range of motion, and ankle function.

Craniosacral Therapy
There was some evidence from 3 small, randomized studies that craniosacral therapy may have a positive effect on tension-type headache pain, infantile colic, and asthma. However, these studies all had significant limitations, including lack of blinding, small sample size, use of largely qualitative or subjective outcome measures, and in 1 study a high dropout rate. The overall level of evidence regarding craniosacral therapy for these indications is weak, and no conclusions regarding the efficacy of this technique can be made. (Hayes, 2009)

Professional Societies
The American Osteopathic Association (AOA): A 2010 guideline recommends osteopathic manipulation be utilized to treat patients with musculoskeletal causes of low back pain such as diagnoses of somatic dysfunctions related to the low back pain. Osteopathic manipulative treatment for somatic dysfunction is utilized only after other potential causes of low back pain are ruled out or considered improbable by the treating physician (i.e., vertebral fracture; vertebral joint dislocation; muscle tears or lacerations; spinal or vertebral joint ligament rupture; inflammation of intervertebral disks, spinal zygapophyseal facets joints, muscles or fascia; skin lacerations; sacroiliitis; ankylosing spondylitis; masses in or from the low back structures; or organic [visceral] disease referring pain to the back or causing low back muscle spasms).

American College of Physicians and the American Pain Society (ACP/APS): Clinical guidelines published jointly by ACP and APS for the diagnosis and treatment of low back pain recommend spinal manipulation for patients who do not improve with self-care options along with a number of other nonpharmacological therapies. (Chou et al., 2007).
A manipulative service is a procedure and therefore not subject to FDA regulation.

Medicare covers manipulative therapy when criteria are met. Refer to the National Coverage Determination (NCD) for Manipulative Therapy (150.1).

Medicare’s coverage for chiropractic services is limited to manual manipulation (i.e., by use of hands) of the spine for the purpose of correcting a subluxation. All other services furnished or ordered by the chiropractor are not covered. For specific coverage requirements, refer to the Medicare Benefit Policy Manual Chapter 15 §30 and §240 available at: http://www.cms.gov/manuals/Downloads/bp102c15.pdf. (Accessed March 17, 2014)

Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. See the LCDs for Chiropractic Services, Osteopathic Manipulative Treatment, Chiropractic Service (Manual Spinal Manipulations) and Medicine: Chiropractic Services (Accessed March 17, 2014)

REFERENCES


Chou R, Qaseem A, Snow V, et al.; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain


Senna MK, Machaly SA. Does maintained Spinal manipulation therapy for chronic non-specific low back pain result in better long term outcome? Spine (Published Ahead of Print) 17 January 2011; doi: 10.1097/BRS.0b013e3181f5dfe0.


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<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>06/01/2014</td>
<td>• Reorganized policy content</td>
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<tr>
<td></td>
<td>• Added benefit considerations language for <em>Essential Health Benefits for Individual and Small Group</em> plans to indicate:</td>
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<tr>
<td></td>
<td>o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (&quot;EHBs&quot;)</td>
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<td>o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans</td>
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<td>o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage</td>
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<td>• Updated coverage rationale:</td>
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<td>o Reformatted and relocated information pertaining to medical necessity review (when applicable); added language to indicate if service is “medically necessary” or “not medically necessary” to applicable proven/unproven statement</td>
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<td>• Updated supporting information to reflect the most current clinical evidence and references</td>
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<td></td>
<td>• Archived previous policy version 2013T0541D</td>
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